PATENT COOPERATION

Reo'd PCT/PT@ 05 MAI 2005

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY 0 8 DEC 2004 CODE DATE NTD GLOBAL INTELLECTUAL PROPE AstraZeneca AB NOTIFICATION OF TRANSMITTAL OF S-151 85 Södertälje HE INTERNATIONAL PRELIMINARY SUEDE **EXAMINATION REPORT** ANKOM 0 6 DEC 2004 GIPS (PCT Rule 71.1) DATA ENTERED Date of mailing FINAL (day/montl/year) 02.12.2004 CHECK Applicant's or agent's file reference IMPORTANT NOTIFICATION 100881-1 WO International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/SE 03/01738 11.11.2003 12.11.2002 ASTRAZENECA AB et al.

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465

Authorized Officer

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 05 MAY 2000

| Applicant's or agent's file reference 100881-1 WO | | | FOR FURTHER ACTIO | N | See Notification Preliminary Ex | n of Transmittal of Internamination Report (Form | ational PCT/IPEA/416) | |
|---|--|--|--|--------------------------------|------------------------------------|--|--------------------------|--|
| | | lication No. | International filing date (day/n | ont | h/year) | Priority date (day/mont | th/year) | |
| PCT/SE 03/01738 | | | 11.11.2003 | 11.11.2003 | | | • | |
| Internati A61K3 | 38/55 | ent Classification (IPC) or b | oth national classification and IP | С | | | | |
| | | CA AB et al. | er er en skriver skriver en skriver en | | | State State of the second | | |
| 1. T | his inter uthority | national preliminary exar and is transmitted to the | nination report has been pre applicant according to Article | par e 36 | ed by this Intel 3. | national Preliminary E | Examining | |
| 2. TI | . This REPORT consists of a total of 4 sheets, including this cover sheet. | | | | | | | |
| | This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). | | | | | | | |
| ТІ | These annexes consist of a total of sheets. | | | | | | | |
| | | | | | | | | |
| 3. Th | nis repo | rt contains indications rel | lating to the following items: | | | - | * *** | |
| i | \boxtimes | Basis of the opinion | | | | | • | |
| 11 | | Priority . | | | | | | |
| 111 | | Non-establishment of o | pinion with regard to novelty | . in | ventive sten a | nd industrial applicabil | lity | |
| IV | <i>'</i> 🗆 | Lack of unity of invention | | • | | Ta mademan applicabil | nty | |
| V | × | Reasoned statement u citations and explanation | nder Rule 66.2(a)(ii) with reg ons supporting such stateme | ard nt | to novelty, inv | entive step or industri | al applicability; | |
| VI | | Certain documents cite | | | | | | |
| Vi | II 🗆 | Certain defects in the in | nternational application | | | | | |
| VI | III 🗆 | Certain observations or | n the international applicatior | 1 | | | ٠ | |
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| Date of s | ubmissio | on of the demand | Data | of c | ampletion of this | | | |
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| 25.05.2 | 25.05.2004 | | | 02.12.2004 | | | | |
| Name an prelimina | ry exami | address of the international | Autho | orize | ed Officer | | gratuctures Petersteap. | |
| D-80298 Munich Engl P | | | | | | | | |
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 03/01738

I. Basis of the report

1. With regard to the **elements** of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

| | Description, Pages | | | | | | |
|----|--|--|--|--|--|--|--|
| | 1-8 | | as originally filed | | | | |
| | | | | | | | |
| • | | ims, Numbers | to the control of the first of the control of the control of the section of the section of the control of the c | | | | |
| | 1-6 | | as originally filed | | | | |
| 2. | Wit lanç | With regard to the language , all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. | | | | | |
| | The | ese elements were ava | ailable or furnished to this Authority in the following language: , which is: | | | | |
| | | the language of a tra | inslation furnished for the purposes of the international search (under Rule 23.1(b)). | | | | |
| | the language of publication of the international application (under Rule 48.3(b)). | | | | | | |
| | | the language of a tra Rule 55.2 and/or 55.3 | nslation furnished for the purposes of international preliminary examination (under 3). | | | | |
| 3. | Witl inte | With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing: | | | | | |
| | | contained in the inter | rnational application in written form. | | | | |
| | | filed together with the | e international application in computer readable form. | | | | |
| | | furnished subsequen | ntly to this Authority in written form. | | | | |
| | | furnished subsequen | atly to this Authority in computer readable form. | | | | |
| | | The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. | | | | | |
| | □ | The statement that the listing has been furni | ne information recorded in computer readable form is identical to the written sequence ished. | | | | |
| 4. | The | amendments have re | esulted in the cancellation of: | | | | |
| | | the description, | pages: | | | | |
| | | the claims, | Nos.: | | | | |
| | | the drawings, | sheets: | | | | |
| 5. | | This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)). | | | | | |
| | | (Any replacement sh report.) | eet containing such amendments must be referred to under item 1 and annexed to this | | | | |
| 6. | Add | itional observations, i | f necessary: | | | | |

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No.

PCT/SE 03/01738

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1-6

Inventive step (IS)

Claims

1-6

Yes: Claims No: Claims

Industrial applicability (IA)

· · · Yes: Claims · · · · · · · · · ·

No: Claims 5,6: see separate sheet

2. Citations and explanations

see separate sheet

INTERNATIONAL PRELIMINARY International application No. PCT/SE 03/01738 EXAMINATION REPORT - SEPARATE SHEET

Concerning Section V:

The intranasal administration of melagatran has been neither taught nor suggested in the available prior art. Novelty and inventive step (Article 33 (2) and (3) PCT) can therefore be acknowledged for the present claimed subject-matter.

Claims 5 and 6 to methods of therapy might be found inadmissible.